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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,307	01/11/2001	Sam J. Milstein	1946/1A483-US8	8759

7590 06/22/2007  
DARBY & DARBY P.C.  
805 Third Avenue  
New York, NY 10022

EXAMINER
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CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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06/22/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

09/760,307

Applicant(s)

MILSTEIN ET AL.

Examiner

Lakshmi S. Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) Claims 13-16, 22-26, 31-36, 50-53, 59-62, 68-73, 87-90, 96-99, 105-110, 112-127, 131-137, 139-150, 152-163, 165-176 and 178-195 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 4-6-07; 6/21/07, 7/16/07, 8/16/07, 9/18/07
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**Continuation of Disposition of Claims:** Claims pending in the application are Claims 13-16, 22-26, 31-36, 50-53, 59-62, 68-73, 87-90, 96-99, 105-110, 112-127, 131-137, 139-150, 152-163, 165-176 and 178-195. .

### **DETAILED ACTION**

Receipt of amendment and response dated 3-27-07 is acknowledged.

Claims 13-16, 22-26, 31-36, 50-53, 59-62, 68-73, 87-90, 96-99, 105-110, 112-127, 131-137, 139-150, 152-163, 165-176 and 178-195.

### ***Response to Arguments***

The following double patenting rejections of record has been maintained:

Claims 13-16, 22-26, 31-36, 50-53, 59-62, 68-73, 87-90, 96-99, 105-110, 112-127, 131-137, 139-150, 152-163, 165-176, and 178-195 stand rejected under the judicially created doctrine of obviousness-type double patenting over various claims of U.S. Patent Nos. 6,071,538; 5,714,116; 6,348,207; 6,221,367; 6,916,489; 7,005,141; 6,461,643; and 5,629,090. Applicants disagree with the rejections. However, applicants state that upon finding an allowable subject matter, a terminal disclaimer will be filed. Since applicants did not present any arguments and because there is no allowable subject matter at this time, the rejections have been maintained.

Applicant's arguments, with respect to the rejection of claim(s) 13-16, 22-26, 31-36, 50-53, 59-62, 68-73, 87-90, 96-99, 105-110, 112-127, 131-137, 139-150, 152-163, 165-176 and 178-195 under 35 USC 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made as follows:

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 13-16, 22-26, 31-36, 50-53, 59-62, 68-73, 87-90, 96-99, 105-110, 112-127, 131-137, 139-150, 152-163, 165-176, and 178-195 are rejected under 35 U.S.C. 103(a) as being unpatentable over in view of US 4,826,817 to Brown et al (Brown) alone or Morishita et al (US Patent No. 4,873,087) in view of Brown.

**Brown** teaches amino acid or hydroxy amino acid as carriers for therapeutic agents such as peptides, dipeptides, proteins, psychotropic agents etc (abstract, col. 1, L52 to col. 2, L55 and col. 5-6). Among the amino acid and hydroxy amino acid carriers, Brown teaches aliphatic, cycloaliphatic or mixed cycloaliphatic aromatic compounds such as those listed in col. 3, L50 through col. 4, L 19), which read on the claimed perturbant. Brown teaches administration of the drugs with the above carriers in several routes such as oral, sublingual, inhalation (col. 9, L 25-36) and also subcutaneous (col. 11, L 40-45).

Instant independent claims recite a method of (subcutaneously, intranasally or sublingually) administering a biologically active agent. Brown teaches all of the above modes of administration.

For the claimed biologically active agents, Brown teaches peptides, proteins, amino acids etc (col. 5-6).

For the claimed step of exposing the active agent to a complexing perturbant, Brown teaches incorporating the amino acid transporter in a composition comprising the above active agents, and accordingly, the formation of a subcutaneously deliverable supramolecular complex is inherent in the teachings of Brown because the reference teaches the same active agents and the amino acid carriers (reads on instant perturbant) as claimed.

**Morishita** teaches a preparation containing an absorption promoter and a medically active agent for promoting absorption through a gastrointestinal organ such as colon, rectum or through vagina. The absorption promoter substance of Morishita is an N-acyl amino acid or N-acyl peptide derivative, of formula I (col. 1, lines 5-10, col. 3, lines 13-15) and is obtained by the reaction of an acid (R-COOH) with an amino acid or peptide. The carboxylic acids and amino acids used for preparing N-acyl amino acids are described in col. 4 and 6 and include those described in the instant specification. Among the medically active agent, Morishita describes hormones, such as insulin, antibiotics etc (col. 5, lines 25-68). Morishita fails to specifically teach that the absorption promoter is non-covalently linked to the active agent or the molecular weight of the promoter. However, Morishita teaches the same components of the instant claims and accordingly the burden is shifted to applicants to show how the teachings of Morishita differ from the instant. Morishita does not specifically teach subcutaneous, intranasal or sublingual delivery routes, instead teaches administration through rectum or vagina, which are lined by mucosal membranes.

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Both Morishita and Brown teach compositions comprising the claimed carriers and various excipients that read on the instant claimed disintegrant, lubricants etc of dependent claims (claim 32, 69 etc). With respect to the specific biologically active agents of dependent claims, Morishita teaches hormones such as insulin, along with several other classes of active agents. Brown teaches that the carriers may be used for any therapeutic agent and accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the amino acid or its derivatives of Brown or Morishita as carriers for delivering therapeutic agents via subcutaneous, intranasal or sublingual routes because Morishita recognizes that the compounds are effective for delivery via mucosal membranes and Brown teaches that the compounds are effective for any or all routes including subcutaneous.

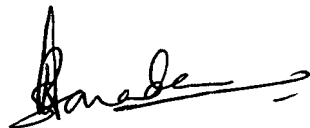
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.00 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AU 1615  
June 15, 2007



LAKSHMI S. CHANNAVAJJALA  
PRIMARY EXAMINER